

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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IN RE PHARMACEUTICAL INDUSTRY	)	MDL No. 1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	Civil Action No.
_____	)	01-CV-12257-PBS
	)	
THIS DOCUMENT RELATES TO	)	
	)	Judge Patti B. Saris
<i>State of Montana v. Abbott Labs., Inc., et al..</i>	)	
<i>02-CV-12084-PBS</i>	)	
_____	)	

**THE JOHNSON & JOHNSON DEFENDANTS'  
INDIVIDUAL MEMORANDUM IN OPPOSITION TO THE  
STATE OF MONTANA'S MOTION FOR PARTIAL SUMMARY JUDGMENT**

Johnson & Johnson, Centocor, Inc., Janssen Pharmaceutica Products L.P., McNeil-PPC, Inc., and Ortho Biotech Products, L.P. (the “J&J Defendants”) submit this memorandum in opposition to the State of Montana’s motion for partial summary judgment. The J&J Defendants incorporate the declarations and Rule 56.1 Statement they submitted in support of their own motion for summary judgment.<sup>1</sup> The J&J Defendants also incorporate the common opposition made on behalf of all defendants.

### **Introduction**

Montana’s motion for partial summary judgment should be denied for the same reasons that the J&J Defendants’ motion for summary judgment should be granted. Montana’s motion turns on the peculiar notion that *any* “spread” between a Medicaid provider’s acquisition cost for a drug (which cost is determined by the wholesaler’s price, not the manufacturer’s price) and Montana’s chosen reimbursement rate (which rate is set by the State, not the manufacturer) is *unlawful*, even though a 30% “spread” between the drug’s published AWP (which is set by the publisher, not the manufacturer)<sup>2</sup> and the provider’s acquisition cost is *lawful*.

This is self-evident nonsense. As set forth in the J&J Defendants’ motion for summary judgment, the State’s expert, Dr. Hartman, has admitted that, in the Medicaid context, a 30% spread between AWP and provider acquisition cost is legitimate and not fraudulent.<sup>3</sup> There is not a shred of evidence that any Johnson & Johnson drug has a spread between AWP and

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<sup>1</sup> These submissions consist of the Supporting Declaration of Andrew D. Schau (“Schau Decl.”), the Johnson & Johnson Defendants’ Individual L.R. 56.1 Statement of Undisputed Facts (“J&J 56.1 Stmt.”), and the Declaration of Jayson S. Dukes Regarding Montana’s Claims (“Dukes Mont. Decl.”).

<sup>2</sup> See Testimony of Patricia Kay Morgan, the Manager of Product Knowledge-Based Services at First DataBank, cited in the Statement of Undisputed Material Facts In Support of Defendants’ Motion for Summary Judgment, and in the Counter 56.1 Statement of Undisputed Facts submitted by AstraZeneca Pharmaceuticals, L.P. (testifying that whatever the drug manufacturers might have thought, First DataBank, not the manufacturers, was responsible for setting the published AWPs).

<sup>3</sup> J&J 56.1 Stmt., ¶ 4. Defendants have disputed Dr. Hartman’s claim that spreads greater than 30% are fraudulent, but that dispute does not undermine the force of Dr. Hartman’s admission that spreads up to 30% are proper.

acquisition cost greater than 30%.<sup>4</sup> Moreover, Montana Medicaid reimburses providers at AWP *minus* 15%. Thus, for Johnson & Johnson's drugs, the difference between the reimbursement amount and the provider's acquisition cost is significantly *below* 30%. This puts Montana in the impossible position of having to argue that spreads up to 30% are simultaneously lawful and unlawful. Undeterred, Dr. Hartman says simply that he was "instructed by counsel" to find liability and damages on spreads he previously said were legitimate.<sup>5</sup> Montana's motion should be denied on that ground alone.

In any event, Montana cannot prevail on its motion because it cannot demonstrate that it suffered any injury or loss as a result of the J&J Defendants' AWP. To the contrary, its alleged "overcharge" damages were completely offset by the rebate payments it received from the J&J Defendants based on the parties' rebate contracts. These rebates more than compensated Montana for the alleged overpayments it made to physicians and pharmacies under its Medicaid program.

### **ARGUMENT**

In order to sustain its claim, Montana must prove that it suffered injury as a result of the J&J Defendants' alleged misreporting of AWP. *Sisler v. Bennett-Ames*, 149 P.3d 944 (Mont. 2006); *In re Estate of Kindsfather*, 108 P.3d. 487 (Mont. 2005). Absent proof of injury, the State may not recover damages or seek statutory penalties. *Id.*

In this case, Montana claims overcharge damages solely with respect to two Johnson & Johnson drugs, Procrit and Remicade. In particular, Montana claims that its Medicaid providers overcharged the Medicaid program \$72,814 for Procrit and \$25,312 for

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<sup>4</sup> J&J 56.1 Stmt., ¶ 3. The Johnson & Johnson spreads listed in Montana's complaint range from 13.4% to 20.8%. Schau Decl. Ex. 1 (Montana Second Amended Complaint, ¶ 489).

<sup>5</sup> Schau Decl. Ex. 5 (Declaration of Raymond S. Hartman (Montana)), ¶¶ 22-23.

Remicade.<sup>6</sup> Montana does not claim overcharge damages with respect to any other Johnson & Johnson drug.<sup>7</sup>

The State's "overcharge" calculations are based on the difference between the reimbursement amount the State paid to its Medicaid providers and the amount the providers paid to pharmaceutical wholesalers to acquire the drugs. But this way of calculating the alleged overcharge ignores the obvious fact that the State's payments are subsidized, in significant part, by the rebates that the J&J Defendants remitted to Montana for drugs administered through its Medicaid program. As the MDL court has noted, damages allegedly incurred due to excessive payments to providers "will necessarily be reduced by the rebates the state received," and, therefore, "may play a role in determining the correct amount of damages in the case." *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 457 F. Supp.2d 65, 74-75 (D. Mass. Sept. 6, 2006).

It is undisputed that, with respect to both Procrit and Remicade, the rebate payments that Montana received from the J&J Defendants *exceeded* (by a substantial margin) the alleged overcharge payments:<sup>8</sup>

**Procrit®**

Alleged "Overcharge" Damages	\$72,814
Rebate Paid	\$146,474
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"Overcharge" Minus Rebate	(\$73,660)

**Remicade®**

Alleged "Overcharge" Damages	\$25,312
Rebate Paid	\$33,566
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"Overcharge" Minus Rebate	(\$8,254)

<sup>6</sup> J&J 56.1 Stmt., ¶ 9.

<sup>7</sup> See Schau Decl. Ex 5 (Declaration of Raymond S. Hartman (Montana)).

<sup>8</sup> Dukes Mont. Decl., ¶ 8.

As a matter of law, absent injury, there is no fraud. Because the rebate payments that Montana received from the J&J Defendants exceed the alleged overcharges, there is no injury.<sup>9</sup> Hence, there is no fraud.

### **CONCLUSION**

The State's motion for partial summary judgment should be denied because there is no record evidence that the modest spreads on the J&J Defendants' drugs were fraudulent, and because the State did not suffer injury because the rebates it received exceeded its alleged overcharge damages.

Dated: March 22, 2007

Respectfully submitted,

/s/ William F. Cavanaugh, Jr.

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<sup>9</sup> It should be noted that Dr. Hartman's estimate of the Montana overcharges are based on ASP calculations that he himself admitted in the MDL were inaccurate. Accordingly, Dr. Hartman revised his ASP calculations before trial. When Dr. Hartman's revised figures are used to calculate the alleged overcharge damages, Montana's alleged damages are reduced by more than \$25,000. *See* Dukes Mont. Decl., ¶ 12.

**Certificate of Service**

I certify that a true and correct copy of the foregoing was served on all parties on  
March 22, 2007 via LexisNexis File & Serve.

/s/ Andrew D. Schau

Andrew D. Schau